



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2000-N-0110]

Bruce I. Diamond; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Dr. Bruce I. Diamond's request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debaring Dr. Diamond for 10 years from providing services in any capacity to a person who has an approved or pending drug product application. FDA bases this order on findings that Dr. Diamond was convicted of felonies under State law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act, was convicted of felonies involving fraud, and was a material participant in acts forming the basis of a conviction that subjects another person to debarment. In determining the appropriateness and length of Dr. Diamond's debarment period, FDA has evaluated the relevant considerations listed in the FD&C Act. Dr. Diamond has failed to file with the Agency information and analysis sufficient to create a basis for a hearing concerning this action.

DATE: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: G. Matthew Warren, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4613.

SUPPLEMENTARY INFORMATION:

I. Background

On December 16, 1997, Dr. Diamond pled guilty to 53 State criminal offenses, including felonies, in the Superior Court for the County of Richmond, Georgia, and the court subsequently entered judgment against him. The offenses in the Official Code of Georgia to which Dr. Diamond pled guilty included 16 counts of theft by taking (section 16-8-2), 10 counts of theft of services (section 16-8-5), 2 counts of written false statements (section 16-10-20), 8 counts of acquiring a controlled substance by misrepresentation (section 16-13-43), 8 counts of prescribing or ordering dangerous drugs (section 16-13-78.1), 7 counts of prescription of controlled substances (section 16-13-41(f)), 1 count of practicing medicine without a license (section 43-34-26), and 1 count of bribery (section 16-10-2). On February 10, 1999, in a separate proceeding, Dr. Diamond consented to disqualification from receiving investigational new drugs under § 312.70 (b) (21 CFR 312.70(b)).

Dr. Diamond, who holds a doctorate in pharmacology but not a medical degree, was a professor on the faculty of the Medical College of Georgia (MCG), a unit of the Board of Regents of the University System of Georgia. Dr. Diamond collaborated with a

colleague there, Richard Borison, M.D., Ph.D., to manage clinical trials for various drug companies. Without the knowledge or consent of MCG, Drs. Diamond and Borison used MCG and other government-owned facilities and State employees to conduct the clinical trials but diverted the funds paid by the study sponsors for their own gain, without compensating the university system. Although Dr. Diamond is not a physician, he managed medical aspects of the clinical trials. In that capacity, he signed Dr. Borison's name on prescriptions for controlled substances and other drugs the State defined as dangerous. During the course of one clinical trial, Drs. Borison and Diamond bribed an employee not to report to MCG an attempted suicide by one of the study subjects.

By notice dated November 26, 2002, FDA proposed to debar Dr. Diamond for 10 years from providing services in any capacity to a person having an approved or pending drug product application. The notice explained that the proposal was based on three separate grounds: (1) Dr. Diamond was convicted of felonies under State law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under the FD&C Act, and the type of conduct serving as the basis of his convictions undermines the process for the regulation of drugs (section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I))); (2) Dr. Diamond was convicted of felonies involving bribery, fraud, and false statement, and, on the basis of the convictions and other information, demonstrated a pattern of conduct sufficient to find that there is reason to believe that he may violate requirements under the FD&C Act relating to drug products (section 306(b)(2)(B)(ii)(I); and (3) Dr. Diamond materially participated in acts that were the basis of Dr. Borison's conviction of offenses subjecting Dr. Borison to

debarment under section 306(b)(2)(B)(ii) and Dr. Diamond's participation, and other information, demonstrate a pattern of conduct sufficient to find that there is reason to believe that he may violate requirements under the FD&C Act relating to drug products (section 306(b)(2)(B)(iii)). The notice to Dr. Diamond also outlined findings with respect to four factors that were considered in determining the appropriateness and period of debarment, as provided in section 306(c)(3) of the FD&C Act: (1) The nature and seriousness of the offense, (2) the nature and extent of management participation in the offense, (3) the nature and extent of voluntary steps to mitigate the impact on the public, and (4) prior convictions under the FD&C Act or other acts involving matters within the jurisdiction of FDA.

By letter dated January 2, 2003, through counsel, Dr. Diamond requested a hearing on the proposal to debar. On February 17, 2004, after FDA granted him extensions, Dr. Diamond submitted a "final response" in support of his request for a hearing on the proposal to debar. In his response, Dr. Diamond argues: (1) That his consent agreement for disqualification under §312.70(b) precludes his debarment, (2) that he is innocent of the charge of bribery, (3) that he is innocent of the charges involving drug prescribing, (4) that assertions that he used unqualified personnel to staff clinical trials are without justification or support, (5) that research subject safety was not compromised under his supervision, and (6) that he did not serve in a managerial role for the criminal conduct because Dr. Borison exercised control over him at all times.

Hearings are granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient

to justify the factual determination urged or the action requested (see § 12.24(b) (21 CFR 12.24(b))).

The Chief Scientist has considered Dr. Diamond's arguments and concludes that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

## II. Arguments

In support of his hearing request, Dr. Diamond presents six issues that we will presume are intended to call into question whether he is subject to debarment--and, if so, whether FDA should debar him--on the basis of any of the three grounds, section 306(b)(2)(B)(i)(I), (b)(2)(B)(ii)(I), and (b)(2)(B)(iii) of the FD&C Act, upon which FDA relied. We therefore address each of his arguments as a challenge to the grounds for debarment or to FDA's conclusions regarding the considerations in section 306(c)(3) of the FD&C Act, as appropriate.

### A. Disqualification Consent Agreement

Dr. Diamond first argues that the consent agreement for his disqualification from receiving investigational drugs under § 312.70(b) precludes his debarment under section 306 of the FD&C Act. In support, he contends that the consent agreement "should have precluded any further administrative action against [him]."

The consent agreement states that the "agreement closes FDA's administrative proceedings in the present matter" (emphasis added). A debarment action under section 306 of the FD&C Act is an entirely separate matter from disqualification proceedings. FDA has the authority to disqualify a researcher from conducting clinical testing of new drugs when it determines that the researcher has repeatedly or deliberately not followed

regulations intended to protect study subjects and ensure data integrity. (See § 312.70(a).) FDA also may debar from the drug industry individuals involved in certain conduct. Once an individual has been debarred, he may no longer provide services in any capacity for anyone with a drug product application that is approved or pending at FDA. (See section 306(a) and (b) of the FD&C Act.)

Furthermore, the consent agreement itself does not foreclose other types of administrative actions, such as debarment under section 306 of the FD&C Act. Finally, there is no statutory basis for concluding that the Agency's decision to disqualify Dr. Diamond from receiving investigational drugs under a separate process precludes his debarment. Accordingly, we conclude that there is no genuine and substantial issue of fact for resolution at a hearing and that the consent agreement regarding Dr. Diamond's disqualification does not prevent his debarment. (See § 12.24(b)(1).)

B. Debarment Under Section 306(b)(2)(B)(i)(I) or 306(b)(2)(B)(ii)(I) of the FD&C Act

Dr. Diamond's next two arguments focus on the conduct underlying his convictions for bribing an employee not to report an attempted suicide by a study subject and unlawfully acquiring and prescribing controlled substances and dangerous drugs. Dr. Diamond does not deny that he was convicted of those offenses, nor does he dispute that this type of conduct subjects him to permissive debarment under the FD&C Act. Rather, he argues that he is innocent of the charges and that "due to his need to reach a plea agreement with the State of Georgia to the charges that he misappropriated money from the State, he entered in to a complex and not wholly supported in fact plea agreement" and he "accepted perhaps too much when he pled guilty."

Section 306(b)(2)(B)(i)(I) of the FD&C Act provides FDA with authority to debar an individual who has been convicted of certain State felonies, if the Agency finds that the type of conduct serving as the basis for the conviction undermines the process for the regulation of drugs. The relevant factual issues are whether Dr. Diamond was, in fact, convicted of a felony under State law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of drug products under the FD&C Act and whether that type of conduct undermines the process for the regulation of drugs. Dr. Diamond does not dispute that he pled guilty to bribery and unlawful prescriptions for controlled substances and dangerous drugs or that this type of conduct undermines the process for the regulation of drugs. Dr. Diamond has therefore failed to show that a genuine and substantial factual dispute exists with respect to FDA's finding that he is subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act.

In the alternative, section 306(b)(2)(B)(ii)(I) of the FD&C Act provides FDA with authority to debar an individual who has been convicted of a felony involving, among other things, bribery, false statements, or fraud, if the Agency finds that the individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products. The relevant factual issues are whether Dr. Diamond was convicted of a felony involving bribery, false statements, or fraud and whether he has demonstrated a pattern of conduct sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products. Dr. Diamond does not dispute that he pled guilty to felonies involving bribery, false statement, and fraud, namely theft of over \$10 million from MCG by an 8-year pattern of deception, bribing an employee, making written false statements,

acquiring controlled substances by misrepresentation, prescribing dangerous drugs and controlled substances while not being a registered practitioner, and practicing medicine without a license. FDA further determined that the type of conduct underlying Dr. Diamond's felony convictions, which were based on the 8-year conspiracy to defraud MCG through a scheme involving clinical studies, demonstrated "a pattern of conduct sufficient to find that there is reason to believe [Dr. Diamond] may violate requirements relating to drug products again." This determination was based on the nature of the conduct underlying the offenses to which Dr. Diamond pled guilty. Dr. Diamond has therefore failed to show that a genuine and substantial factual dispute exists with respect to FDA's finding that he is subject to debarment under section 306(b)(2)(B)(ii)(I) of the FD&C Act.

Section 306(l) of the FD&C Act includes in its definition of a conviction, a guilty plea. Accordingly, Dr. Diamond's arguments regarding the factual circumstances underlying his plea fail to raise a genuine and substantial issue of fact as to whether he was convicted of a felony under State law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act or whether he was convicted of a felony involving bribery, false statements, or fraud. Dr. Diamond contends that his plea agreement was "not wholly supported in fact." In his Written Plea of Guilty, however, Dr. Diamond states that "of my own free will I want to plead guilty today to the offenses [enumerated] . . . know and understand that I do not have to say, sign, or do anything that will show or tend to show that I am guilty unless I want to . . . My decision to plead guilty is freely and voluntarily made . . . I did in fact commit the offenses of which I am charged. I am in fact guilty as

charged in the indictment and am in fact guilty of the charges I am pleading guilty to.”

He also stated that he was advised by competent counsel regarding his constitutional and due process rights. He was examined by the court during a lengthy plea colloquy. Under these circumstances, and in light of the court’s acceptance of his guilty plea, Dr.

Diamond’s allegations that he was actually innocent of the offenses and that he signed a plea agreement that was not wholly truthful are insufficient to create a genuine and substantial issue of fact for resolution at a hearing. (See § 12.24(b)(1) and (b)(2).)

Therefore, Dr. Diamond is subject to debarment.

C. Debarment Under Section 306(b)(2)(B)(iii) of the FD&C Act

Finally, FDA found that Dr. Diamond is subject to debarment under section 306(b)(2)(B)(iii) of the FD&C Act for his material participation in the acts that resulted in another’s conviction for an offense described in section 306(b)(2)(B)(ii)(I) and that on that basis, Dr. Diamond had demonstrated a pattern of conduct sufficient to support a belief that he would violate requirements under the FD&C Act relating to drug products. On September 30, 2003, FDA debarred Dr. Diamond’s co-conspirator, Dr. Borison, under section 306(b)(2)(B)(ii)(I) of the FD&C Act, for his conviction of felonies under State law for racketeering, theft, and false statements and representations. (See Richard L. Borison; Debarment Order, 68 FR 56298 (September 30, 2003).) Dr. Diamond does not deny his material participation in the conduct that led to Dr. Borison’s conviction. In particular, he does not deny participating with Dr. Borison in the theft of over \$10 million from MCG via an 8-year pattern of deception involving clinical trials. Furthermore, he does not dispute that his behavior demonstrates a pattern of conduct sufficient to support a finding that he would violate requirements under the FD&C Act

relating to drug products. Dr. Diamond has therefore failed to show that a genuine and substantial factual dispute exists with respect to FDA's finding that he is subject to debarment under section 306(b)(2)(B)(iii) of the FD&C Act.

#### D. Debarment Considerations

Next, we construe Dr. Diamond's arguments regarding his innocence of the charges of bribery and unlawful prescriptions to be challenges to FDA's findings with respect to the debarment considerations of section 306(c)(3) of the FD&C Act. Dr. Diamond's arguments regarding the training and qualifications of the staff he oversaw as part of his criminal scheme and the safety of the subjects who participated in the clinical studies also seem to be directed at those findings. As noted previously, he also challenges FDA's finding that he participated as a manager in the offenses involved because, he claims, Dr. Borison controlled him and masterminded the entire criminal operation.

Section 306(c)(3) of the FD&C Act requires that FDA consider, "where applicable," certain factors "[i]n determining the appropriateness and the period of debarment" for any permissive debarment. The proposal to debar Dr. Diamond set forth four applicable considerations under section 306(c)(3) of the FD&C Act: (1) The nature and seriousness of his offense under section 306(c)(3)(A), (2) the nature and extent of management participation in the offense under section 306(c)(3)(B), (3) the nature and extent of voluntary steps taken to mitigate the impact on the public under section 306(c)(3)(C), and (4) prior convictions involving matters within the jurisdiction of FDA under section 306(c)(3)(F).

In its proposal to debar, FDA presented factual findings relevant to each of the considerations. FDA determined, under section 306(c)(3)(A) of the FD&C Act, that the nature and seriousness of Dr. Diamond's offenses weighed in favor of debarment because of the scope of his criminal conduct, his prescription of drugs without a practitioner's license, and his direction of inadequately trained staff to perform medical procedures, creating a risk of injury. The Agency found, under section 306(c)(3)(B) of the FD&C Act, that Dr. Diamond's management participation in the offenses weighed in favor of debarment. The Agency found that Dr. Diamond was a manager in that he "plann[ed] . . . , directed, and initiated the conduct underlying [his] conviction" and "directed other MCG employees to recruit subjects and participate in the conduct of the clinical studies." Under section 306(c)(3)(C) of the FD&C Act, the Agency determined that, although Dr. Diamond cooperated with the authorities once they discovered his criminal scheme, he did not "promptly disclose to authorities all wrongdoing" and exhibited a wanton disregard for the public health by bribing an employee to remain silent about a suicide attempt. This factor also was found to weigh in favor of disbarment. Finally, relating to section 306(c)(3)(F) of the FD&C Act, FDA noted that the Agency is unaware of any prior convictions under the FD&C Act, a favorable factor.

Dr. Diamond first appears to challenge these findings by arguing that he is actually innocent of the bribery and unlawful prescriptions charges. As noted previously, however, his claims of actual innocence do not create a genuine and substantial issue of fact, as they must to justify a hearing under § 12.24(b). Dr. Diamond pled guilty to those offenses in Federal Court, and he is bound by his guilty pleas, notwithstanding his current arguments that he pled guilty to those offenses only for strategic reasons.

Dr. Diamond also contests the Agency's characterization of the conduct underlying his criminal convictions, as well as his material participation in the offenses committed by Dr. Borison. However, in pleading guilty to 52 criminal offenses, Dr. Diamond admitted to certain conduct. The conduct to which he admitted during the plea colloquy included overseeing a staff of nine employees to assist in running the clinical trials, bribing an employee not to report an adverse event, and prescribing controlled substances without a medical license. The offenses to which Dr. Diamond pled guilty stemmed from an 8-year scheme to deceive a medical college and his concurrent disregard for the protection of patients afforded by State laws.

By contending that the employees he oversaw did, in fact, have adequate training in drawing blood and that his conduct did not compromise the safety of any patients, Dr. Diamond is challenging FDA's proposed findings regarding the nature and seriousness of any offenses involved under section 306(c)(3)(A) of the FD&C Act and the nature and extent of voluntary steps taken to mitigate the effect on the public under section 306(c)(3)(C). Even assuming, as Dr. Diamond now argues, that the nine employees he oversaw had received adequate training in drawing blood and that no patient was actually harmed by Dr. Diamond's conduct, the 8-year scheme in which he participated still evinces both a clear disregard for the laws designed to protect patients and the public at large and a willingness to commit fraud in furtherance of his own financial gain. Dr. Diamond had 8 years to voluntarily mitigate the effects of his wrongdoing but failed even to modify his behavior to protect the public. Furthermore, Dr. Diamond's arguments that he did not compromise the safety of his patients are belied by his convictions for violating numerous State criminal statutes clearly aimed at protecting patients, such as

practicing medicine without a license and unlawfully acquiring and prescribing controlled or dangerous drugs. In short, given the scope of Dr. Diamond's conduct, his current claims regarding the training of his employees and the safety of his patients are inadequate to create a genuine and substantial issue of fact with respect to the considerations in sections 306(c)(3)(A) and (c)(3)(C) or, more generally, the appropriateness or period of his proposed debarment.

Finally, Dr. Diamond challenges the Agency's findings under section 306(c)(3)(B) of the FD&C Act that he participated as a manager in his offenses by arguing that Dr. Borison exercised control over him and masterminded the criminal scheme. As noted previously and as outlined in the indictment to which he pled guilty, however, Dr. Diamond served a managerial role in the offenses. Even assuming, as Dr. Diamond now alleges, that he was at all times second in command to Dr. Borison, Dr. Diamond admitted during his criminal proceedings that he oversaw a staff of at least nine employees in implementing the criminal scheme of which he was convicted. Furthermore, he does not dispute the findings in the proposal to debar that he, along with Dr. Borison, was involved in planning and initiating the criminal scheme. Dr. Diamond's claim that he was "at all times subservient to Dr. Borison" fails to present a genuine and substantial issue of fact with respect to the consideration in section 306(c)(3)(B) of the FD&C Act or, more generally, the appropriateness or period of his proposed debarment.

Consistent with the findings in the proposal to debar, the Chief Scientist finds, based on the undisputed record before the Agency, that debarment of Dr. Diamond for two consecutive terms of 5 years is appropriate. The considerations in section 306(c)(3)(A), (c)(3)(B), and (c)(3)(C) of the FD&C Act weigh in favor of debarring Dr.

Diamond for at least 10 years. Although Dr. Diamond appears to have no previous criminal convictions related to matters within the jurisdiction of FDA (see section 306(c)(3)(F) of the FD&C Act), that consideration does not counter to a sufficient degree the remaining considerations to warrant decreasing the periods of debarment. Of particular note are the nature and seriousness of Dr. Diamond's offenses. As detailed previously, Dr. Diamond pled guilty to an 8-year criminal scheme reflecting not only, as found in the proposal to debar, "a wanton disregard for the public health," but also a willingness to defraud a government body over a sustained period of time. Reducing the period of debarment from 10 years to some lesser amount of time based on Dr. Diamond's lack of prior criminal convictions would be inconsistent with protecting the public health and thus the remedial purpose of the Agency's debarment authority under section 306 of the FD&C Act.

## II. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act, or in the alternative section 306(b)(2)(B)(ii)(I) and (b)(2)(B)(iii) and under authority delegated to him, finds that Dr. Diamond is subject to debarment. The Chief Scientist has considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that debarment for 10 years is appropriate.

As a result of the foregoing findings, Dr. Diamond is debarred for 10 years from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see DATES) (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any

person with an approved or pending drug product application who knowingly uses the services of Dr. Diamond, in any capacity during his period of debarment, will be subject to civil money penalties. If Dr. Diamond, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Diamond during his period of debarment.

Any application by Dr. Diamond for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA-2000-N-0110 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain documents in the Docket at <http://www.regulations.gov/>.

Dated: November 4, 2013.

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Jesse L. Goodman,  
Chief Scientist.

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